

REMARKS

Claims 1-58 and 61-106 are pending herein. By this Amendment, Claims 59-60 are canceled; Claims 21, 26-29, 46-47, 53-55, 57-58, 62, 66-67, and 81-82 are amended; and new Claims 96-106 are added. Support for the claim amendments is found in the specification at, *inter alia*, page 12, lines 4-26; page 14, lines 28-30; page 15, lines 1-8; page 16, lines 15-19; and page 18, lines 2-12. No new matter is added by this Amendment. A Version With Markings To Show Changes Made is attached.

Applicant thanks Examiner Webman for the courtesies extended to their representative during the May 23, 2002 personal interview. Applicants' separate record of the interview is set forth in the foregoing amendments and the following remarks.

I. PROSECUTION HISTORY OF PENDING CLAIMS

In response to a first Restriction Requirement dated March 5, 2000, Applicants elected Group II, directed to Claims 21-29 and 46 and added new Claims 47-67.

In response to a second Restriction Requirement dated August 7, 2000, Applicants elected Group I, directed to Claims 21-27, 29, 47-60, and 66-67, the durum wheat species of plasticizable matrix material, and the enzyme neutraceutical species. The second Restriction Requirement was withdrawn and a third Restriction Requirement was issued dated January 19, 2001.

In response to the third Restriction Requirement, Applicants elected Group I, Claims 21-27, 29, 47-60, and 66-67, the durum wheat species of plasticizable matrix material, and the microorganism neutraceutical species.

In a first Office Action dated July 5, 2001, Claims 21-22, 24-25, 28-29, 47-52, 54-60, and 66-67 were examined. In an Amendment filed on November 5, 2001, Claims 15 and 28 were amended and new Claims 69-95 were added.

In a second, non-final Office Action dated April 1, 2002, Claims 21-22, 26, 29, 47-52, 54-55, 57, 59, and 66-67 were examined.

II. THE THIRD RESTRICTION REQUIREMENT IS IN ERROR

The encapsulated product (Claim 21) is in an intermediate-final product relationship with the food composition (Claim 28). According to MPEP 806.04(b), which was cited by the Examiner, an intermediate typically loses its identity in the final product. However, the claimed encapsulated product does not lose its identity in the food composition or edible product. Further, the combination claim (food composition) require the particulars of the subcombination claim (encapsulated product) for patentability. Further, as discussed at the interview, Claim 46 recites the elected species of plasticizable matrix material (durum ingredient) and encapsulant (live microorganism). Accordingly, the restriction requirement is in error, and Applicants respectfully request examination of Claims 28, 46, and 61-65 with Claims 21-27, 29, 47-58, and 66-67. Also, if the product claims are found allowable, the Examiner is respectfully requested to reconsider the restriction requirement so as to rejoin claims directed to methods for making the products.

I. FORMAL MATTERS

Claims 21-22, 47-52, 54 and 66-67 were rejected under 35 U.S.C. 112, second paragraph, as assertedly being indefinite.

Claims 21 and 46 are amended to recite a durum ingredient. Regarding Claims 21 and 66-67, Applicants respectfully note that the word "substantially" is not indefinite. See MPEP 2173.05(b)(D). It is well-settled that the term "substantially" is definite without any quantitative or numerical definition, so long as one of ordinary skill in the art

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understands what is claimed. *In re Nehrenberg*, 280 F.2d 161 (CCPA 1960); *In re Mattison*, 509 F.2d 563 (CCPA 1975). The ordinary and accustomed meaning of “substantially” is well established and is accepted as definite. See *York Products, Inc. v. Central Tractor Farm & Family Center*, 99 F.3rd 1568, 1573 (Fed.Cir. 1996); *Pall Corp. v. Micron Seps.*, 66 F.3rd 1211, 1217 (Fed.Cir. 1995); *Andrew Corp. v. Gabriel Elecs. Inc.*, 847 F.2d 819 (Fed. Cir 1988). Even without *any* description or definition of “substantially” in the specification or claims, the Court in *Pall Corp.* and in *Andrew Corp.* found that, like the term “about,” the term “substantially” is a descriptive term commonly used in patent claims to “avoid a strict numerical boundary to the specified parameter”.

Accordingly, the scope of Claims 21-22, 47-52, 54, and 66-67 would be reasonably ascertainable to one of ordinary skill in the art when read in light of the specification. Thus, the requirements of 35 U.S.C. 112 are satisfied. Reconsideration and withdrawal of the rejection are respectfully requested.

II. REJECTIONS UNDER 35 U.S.C. 102(b) AND 103(a)

Claims 21-22, 26, 29, 47-52, 54, and 66-67 were rejected under 35 U.S.C. 102(b) over U.S. Patent No. 5,074,902 (Connick).

Connick discloses a weed pathogenic fungi that is encapsulated in a wheat gluten matrix. The encapsulated fungi grow onto the surface of the formed products when provided with sufficient light and water (Abstract). Connick does not teach or suggest an encapsulated product comprising a hydrophobic agent for controlling the rate of release of the encapsulant or an edible product. The claimed hydrophobic agent helps delay penetration of water or gastric juices into the plasticized matrix (specification at page 15, lines 15-18). In contrast, the objective in Connick is to expose the fungi to water and light so that they will grow (Abstract; col. 4, lines 23-25). Thus, it would not have

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been obvious for one of ordinary skill in the art to make the claimed encapsulated products, food products, and edible products in view of the teachings of Connick. Reconsideration and withdrawal of the rejection are respectfully requested.

Claims 21-22, 24, 29, 47-52, 54-55, 57, 59, and 66-67 were rejected under 35 U.S.C. 103(a) over U.S. Patent No. 5,320,669 (Lim) in view of U.S. Patent No. 3,928,567 (Andersen).

Lim discloses a biodegradable thermoplastic composition made of a cereal grain and may contain 2 wt.% or less of lubricant additives (col. 6, lines 7-26). The molded articles may be used for packaging drugs (col. 9, line 14). Lim does not teach or suggest an encapsulated product comprising a substantially homogeneous mixture of (1) at least one plasticized matrix material, (2) an encapsulant, and (3) a hydrophobic agent, as recited in Claim 21. Lim also does not teach or suggest an encapsulated product comprising about 5% to 70% by weight of a hydrophobic agent for controlling the rate of release of the encapsulant, as recited in Claim 101. Finally, Lim does not teach or suggest that a liquid encapsulant component comprising the encapsulant and a liquid plasticizer provides at least a substantial portion of liquid plasticizer for forming the at least one plasticized matrix material, as recited in Claim 104.

Andersen does not overcome the deficiencies of Lim. Andersen discloses a compressed tablet that contains Brewer's yeast (Abstract). There is no teaching or suggestion to place the Brewer's yeast of Andersen into a packaging article as disclosed in Lim. Lim has nothing to do with Brewer's yeast. In particular, Lim states that the packaging article may be used for drugs having moderate amounts of water (col. 9, line 15). Even if the two references are properly combinable, which they are not, Andersen also does not teach or suggest an encapsulated product comprising a homogeneous mixture of at least one plasticized matrix material, an encapsulant, and a hydrophobic

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agent, as recited in Claim 21. Further, Andersen does not teach or suggest (1) an encapsulated product comprising about 5% to 70% by weight of a hydrophobic agent, or (2) that a liquid encapsulant component comprising the encapsulant and a liquid plasticizer provides at least a substantial portion of liquid plasticizer for forming the at least one plasticized matrix material. Thus, it would not have been obvious for one of ordinary skill in the art to make the claimed encapsulated products, food products, and edible products in view of the combined teachings of Lim and Andersen.

Reconsideration and withdrawal of the rejection are respectfully requested.

III. DOUBLE-PATENTING REJECTION

Claim 42 was provisionally rejection under the judicially-created doctrine of obviousness-type double patenting over claims of copending Application No. 09/782,320.

As discussed at the interview, Claim 42 is a non-elected method claim and the Examiner said he would reconsider this rejection in view thereof. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. CONCLUSION

In light of the foregoing remarks, this application should be in condition for allowance, and early passage of this case to issue is respectfully requested. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application.

A Supplemental Information Disclosure Statement is being filed concurrently herewith.

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A check is enclosed in the amount of \$246.00 for additional claim fees. If any fees are due, please charge our Deposit Account No. 501032 (Docket No. BVL-105).

Respectfully submitted,



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Enclosures: Version with Markings
to Show Changes Made
Check for \$246.00

CERTIFICATE OF MAILING

I hereby certify that this correspondence dated 7/1/02 is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on 7/1/02.



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IN THE CLAIMS:

Please cancel Claims 59-60, without prejudice to or disclaimer of the subject matter therein.

Please amend Claims 21, 26-29, 46-47, 53-55, 57-58, 62, and 66-67 as follows:

21. (Amended) An encapsulated product [obtained by the method of claim 1 which is in substantially non-expanded, particulate form] comprising a substantially homogeneous mixture of:

at least one plasticized matrix material comprising a durum ingredient [, and];

[wherein said] an encapsulant that is at least one [heat sensitive] component selected from the group consisting of a pharmaceutical component, neutraceutical component, nutritional component, flavor component, fragrance component, [or] and biologically active component[, and said plasticizable matrix material comprises durum wheat]; and

a hydrophobic agent for controlling the rate of release of the encapsulant,
wherein said encapsulated product is in substantially non-expanded, particulate form.

26. (Amended) An encapsulated product [obtained by the method of claim 1] according to claim 21, wherein said encapsulant is at least one member selected from the group consisting of antioxidants, phytochemicals, hormones, vitamins, pro-vitamins, minerals, microorganisms, prebiotics, probiotics, trace elements, essential and/or highly

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unsaturated fatty acids, antibiotics, nutritional supplements, enzymes, formulations containing zidovudine, macromolecular polypeptides, aromatic nitro and nitroso compounds and their metabolites useful as anti-viral and anti tumor agents, HIV protease inhibitors, antibiotics, viruses, pigments, steroids, oligopeptides, dipeptides, amino acids, flavor components, fragrance components, detergents and surface-active components, lipid derivatives of phosphonatides, amphiphilic polymers, adenosine derivatives, sulfated tannins, monoclonal antibodies, and metal complexes of water-soluble texathyrin.

27. (Amended) An encapsulated product [obtained by the method of claim 1] according to Claim 100, wherein said encapsulant is at least one member selected from the group consisting of amylases, proteases, lipases, pectinases, cellulases, hemicellulases, pentosanases, and phytases.

28. (Amended) A food composition comprising:
an encapsulated product [obtained by the method of claim 1] according to Claim 21; and
a food product [which is] selected from the group consisting of ready-to-eat breakfast cereals, snacks, soups, salads, cakes, cookies, crackers, ice creams, yogurts, puddings, custards, baby foods, medicinal foods, sports bars, and beverages.

29. (Amended) A food topping comprising an encapsulated product according to Claim 21 [obtained by the method of claim 1] in granular form.

46. (Amended) An edible product for human or animal consumption comprising

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an encapsulated product, said encapsulated product being obtained by admixing (a) at least one plasticizable matrix material, (b) a liquid plasticizer, (c) an encapsulant, (d) a matrix component which is substantially non-plasticizable at temperatures lower than the decomposition temperature of the encapsulant, and (e) at least one component for controlling the rate of release of the encapsulant,

wherein the substantially non-plasticizable matrix component comprises an at least substantially non-gelatinized starch,

wherein said at least one plasticizable matrix material comprises at least one member selected from the group consisting of high gluten content flours, gluten from wheat, durum wheat, durum semolina, pregelatinized starch, pentosans, hydrocolloids, and mixtures thereof, and

wherein said encapsulant comprises at least one member selected from the group consisting of enzymes, vitamins, micronutrients, and live microorganisms.

47. (Amended) An encapsulated product as claimed in claim 21 wherein the encapsulated product is obtained from a formable mixture which is extruded through a die having multiple apertures, at a rate of extrudate per die area of less than about 5 kg/h per mm².

53. (Amended) An encapsulated product as claimed in claim [21] 104, wherein said liquid encapsulant component comprises at least one enzyme.

54. (Amended) An encapsulated product as claimed in claim 21, wherein the amount of said at least one [plasticizable] plasticized matrix material is at least about 30 % by weight based upon the weight of [said dry pieces] the encapsulated product.

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55. (Amended) An encapsulated product as claimed in claim [26] 104, wherein said at least one plasticizable matrix material [which] is admixed with said liquid encapsulant component [is] in solid form.

57. (Amended) An encapsulated product as claimed in claim 26, wherein the amount of said at least one [plasticizable] plasticized matrix material is at least about 30 % by weight based upon the weight of [said dry pieces] the encapsulated product.

~~58. (Amended) An encapsulated product as claimed in claim 27, wherein the amount of said at least one [plasticizable] plasticized matrix material is at least about 30 % by weight based upon the weight of [said dry pieces] the encapsulated product.~~

2, 62. (Amended) An edible product as claimed in claim 46 wherein said at least one plasticizable matrix material comprises at least one member selected from the group consisting of high gluten content flours, gluten from wheat, durum [wheat] flour, and durum semolina.

66. (Amended) An encapsulated product [obtained by the method of claim 1] according to Claim 47 [which is in substantially non-expanded, particulate form] wherein said formable mixture is extruded by a single screw or twin screw extruder.

67. (Amended) An encapsulated product [obtained by the method of claim 1] according to Claim 47 [which is in substantially non-expanded, particulate form]

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wherein said formable mixture is obtained by admixing [said] ingredients in an extruder and the formable mixture is extruded from the extruder to obtain [said] pieces.

~~81.~~ (Amended) A method as claimed in claim [81] 80, wherein the rate of extrudate per die area is less than 3 kg/h per mm².

~~82.~~ (Amended) A method as claimed in claim [82] 80, wherein the rate of extrudate per die area is less than about 0.5 kg/h per mm².

New Claims 96-106 are added.